

Exhibit 15

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.
Civil Action No. 07-10248-PBS

Exhibit to the August 28, 2009 Declaration of James J. Fauci In Opposition To
Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc.
Local Rule 56.1 Statement of Undisputed Material Facts
in Support of Their Motion For Summary Judgment

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION
PRICE LITIGATION) 01-CV-12257-PBS

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THIS DOCUMENT RELATES TO)
United States of America, et al.,) Judge Patti B.
Ven-a-Care of the Florida Keys,) Saris
Inc.,)
vs.)
Boehringer Ingelheim, Corp.,) Chief Magistrate
et al.) Judge Marianne B.
Civil Action 07-10248-PBS) Bowler

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(Cross-caption appears on following page)

VIDEOTAPED DEPOSITION OF SHELDON BERKLE

VOLUME I

Naples, Florida

Friday, October 31, 2008

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1 IN THE COURT OF THE SECOND JUDICIAL CIRCUIT

2 IN AND FOR LEON COUNTY, FLORIDA

3 -----X

4 THE STATE OF FLORIDA ex rel.)

5 VEN-A CARE OF THE FLORIDA KEYS,)

6 INC., a Florida Corporation, by)

7 and through its principal)

8 officers and directors, ZACHARY)

9 T. BENTLEY and T. MARK JONES)

10 Plaintiffs,) CIVIL ACTION

11 vs.) NO. 98-3032A

12 BOEHRINGER INGELHEIM CORPORATION,)

13 et al.)

14 Defendants.)

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1 A. Yes, there was.

2 Q. When was that?

3 A. It was November 1994.

4 Q. And when did you stop working for
5 Boehringer Ingelheim's American operations?

6 A. The end of 2003.

7 Q. Upon transfer to the U.S., which
8 specific entity did you work for?

9 A. BIPI.

10 Q. BIPI. What was your position there?

11 A. Executive vice president.

12 Q. Executive vice president.

13 Did you have -- Did you have a position
14 at any other Boehringer Ingelheim entities in
15 America at that time?

16 MR. GASTWIRTH: Objection to form.

17 THE DEPONENT: I was a vice president
18 for BI Corporation.

19 BY MR. FAUCI:

20 Q. Is it okay if we refer to that as BIC?

21 A. Sure.

22 Q. What about a company known as Roxane

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1 Laboratories, did you have a position with them?

2 MR. GASTWIRTH: Objection to form.

3 THE DEPONENT: No.

4 BY MR. FAUCI:

5 Q. Can you describe in general the
6 business of BIPI in the 1994 time frame. By
7 business I mean, among other things, what types
8 of products was the company marketing or selling?

9 A. Again, it was involved in the research;
10 basic research, clinical research and marketing
11 sales of human pharmaceuticals. It was a
12 relatively smaller company in the U.S.
13 pharmaceutical business. And we were involved in
14 a couple therapeutic areas at that point,
15 respiratory medicine predominantly.

16 Q. Were most of BIPI's products branded
17 drugs or generic drugs?

18 A. Branded drugs.

19 Q. Can you describe the business of BIC at
20 about the same time, the 1994 time frame.

21 A. My understanding of what BIC was was
22 really as a holding company for the U.S.

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1 Q. Can you tell me what the difference is
2 between a multi-source or --

3 MR. GASTWIRTH: Just hold on for one
4 second.

5 MR. FAUCI: Sure.

6 MR. GASTWIRTH: Okay. Thanks.

7 BY MR. FAUCI:

8 Q. Can you tell me the difference between
9 a multi-source or generic product and a branded
10 generic product.

11 A. Again, my understanding is a multi-
12 source product is a product in which there are
13 several companies marketing the same chemical
14 entity with really no differentiation in terms of
15 the quality aspects of those drugs.

16 Branded generics in my estimation is
17 then again not so different in the sense that
18 these products are still marketed by multiple
19 companies; however, there is a brand name
20 attached to that generic drug and there is an
21 attempt to try to differentiate those branded
22 generics from each other.

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1 Q. I believe your testimony earlier was
2 that Roxane was not included within the business
3 unit; is that correct?

4 A. I believe I said that it was a separate
5 division.

6 Q. Can you elaborate what you mean by
7 that.

8 A. Roxane was a separate business entity.
9 They had their own budgets, their own plans. Any
10 involvement that I had was really on a strategic
11 level with Roxane.

12 Q. So is it your testimony that the
13 business unit was just limited to BIPI?

14 A. The business unit was primarily BIPI
15 plus a strategic oversight of Roxane, but Roxane
16 had its own management team and it was
17 responsible for the annual budgets, marketing
18 plans, day-to-day operations.

19 Q. But at least on a strategic level -- Is
20 it fair to say that on a strategic level Roxane
21 sat within the business unit?

22 MR. GASTWIRTH: Objection to form.

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1 THE DEPONENT: I don't think I would
2 use the term "sat." They had a separate physical
3 presence, separate facilities. And within the
4 strategic oversight, yes.

5 BY MR. FAUCI:

6 Q. What is OPINA?

7 A. OPINA is an acronym that stood for the
8 optimization of the pharmaceutical business
9 within North America.

10 Q. The two -- I'm going to read again just
11 from the end of that paragraph. It says, The two
12 leading entities, BIPI and Roxane -- I'm sorry,
13 I'm going to go back a little bit before.

14 Of primary importance to this position
15 will be, and then it says among other things, the
16 maximizing of synergies of the two leading
17 entities, BIPI and Roxane. Were there synergies
18 between BIPI and Roxane?

19 A. Certainly not -- not at the -- not when
20 I first came in '94. There really were two
21 separate businesses.

22 Q. Did you view as one of your goals when

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1 you were hired to maximize synergies between the
2 two companies?

3 A. I -- Again, I -- Certainly at that
4 point in time my primary focus was on building
5 the branded human pharmaceutical business within
6 BIPI. And certainly one of my -- one of my
7 objectives was to look down the road as to
8 whether there were, in fact, any synergies
9 between the BIPI operation and the Roxane
10 operation.

11 Q. And down the road were there any
12 synergies that could be exploited or --

13 A. Yeah. We --

14 MR. GASTWIRTH: Objection to form.

15 THE DEPONENT: We certainly did look at
16 certain things where we were able to create some
17 synergies, yes.

18 BY MR. FAUCI:

19 Q. Was this a -- a goal that-- was one of
20 the goals that you were hired for, to look into
21 improving the synergies or exploiting or finding
22 synergies between these companies?

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1 MR. GASTWIRTH: Objection to form.

2 THE DEPONENT: The primary reason why I
3 was brought to the U.S. was really to grow the
4 branded pharmaceutical business within BIPI.

5 BY MR. FAUCI:

6 Q. That was the primary reason?

7 A. Right. Primary reason.

8 Q. Was coordinating or improving upon the
9 synergies between BIPI and Roxane a reason that
10 you were hired?

11 A. Yes.

12 Q. If you turn to the next page of Exhibit
13 2. Do you see where it says basic
14 responsibilities, essential functions?

15 A. Yes, I do.

16 Q. Can you read into the record the third
17 bullet point.

18 A. The one that begins with "insures
19 optimization"?

20 Q. That's correct.

21 A. Sure. Insures optimization of
22 performance in the U.S. through the development

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1 and direction of innovative strategies and
2 tactics for BIPI and RLI, including prescription
3 OTC switches and activities to defend brand name
4 products from generic erosion.

5 BY MR. FAUCI:

6 Q. Is RLI Roxane?

7 A. Yes, it is.

8 Q. It's okay if we refer to both terms
9 interchangeably today, RLI, Roxane, they both
10 mean Roxane Laboratories?

11 A. Yes.

12 Q. What are RX/OTC switches?

13 A. Again, that refers to products that are
14 originally prescription drugs, drugs that must be
15 prescribed by a physician. And sometimes when
16 drugs have been on the market for a long period
17 of time, have established a solid safety record,
18 you can approach the FDA and determine if you
19 can, in fact, transition that product or those
20 products from a prescription basis to over-the-
21 counter basis so that you can buy them in the
22 pharmacy without a prescription.

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1 THE DEPONENT: It's possible.

2 BY MR. FAUCI:

3 Q. Do you have any reason to believe it
4 wasn't sent to Roxane employees?

5 A. I don't know whether it was or wasn't
6 to be honest with you.

7 Q. Do you see at the second page that this
8 document was signed by--I might mispronounce his
9 name--Werner Gerstenberg?

10 A. Yes. And that's correct by the way.

11 Q. Thank you.

12 Who is Mr. Gerstenberg?

13 A. Mr. Gerstenberg was the CEO of
14 Boehringer in the United States.

15 Q. And by Boehringer in the United States,
16 do you mean BIPPI?

17 A. I mean all the divisions. The total
18 company.

19 Q. So was he the CEO of BIC?

20 A. You know, again, I don't know what the
21 legal aspects were, but he was basically the
22 overall country manager for the United States.

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1 Q. Including Roxane?

2 A. Including Roxane.

3 Q. Did you report to Mr. Gerstenberg?

4 A. Yes, I did.

5 Q. Was there anyone in between you and Mr.
6 Gerstenberg in the hierarchy of the corporation
7 or were you pretty much directly reporting to
8 him?

9 MR. GASTWIRTH: Objection to form.

10 THE DEPONENT: I reported directly to
11 Mr. Gerstenberg.

12 BY MR. FAUCI:

13 Q. On the first page in the fourth
14 paragraph down, can you just read the first
15 sentence into the record.

16 A. Starting with Shelly's duties?

17 Q. Yes. Thank you.

18 A. Shelly's duties will mainly focus on
19 the strategic alignment of our ethical
20 pharmaceutical business in the U.S. and he will
21 be responsible for the operating result for this
22 area.

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1 BY MR. FAUCI:

2 Q. Were you an officer at any other -- any
3 other Boehringer Ingelheim companies besides BIPI
4 and BIC?

5 MR. GASTWIRTH: Objection to form.

6 THE DEPONENT: No.

7 BY MR. FAUCI:

8 Q. Which company paid your salary?

9 A. I believe it was BIPI that paid my
10 salary.

11 Q. Did you receive a salary from BIC?

12 A. No.

13 Q. Did you sit on any boards of directors
14 for Boehringer Ingelheim companies?

15 MR. GASTWIRTH: Objection to form.

16 THE DEPONENT: The only board -- The
17 only direct position I believe I had was with --
18 was with Roxane Laboratories.

19 BY MR. FAUCI:

20 Q. Do you know approximately how long you
21 served on the Roxane board?

22 A. Off the top of my head I can't

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1 remember. It may be a few years, but I can't
2 remember specifically.

3 Q. Do you remember anyone else who served
4 on the board?

5 A. Of?

6 Q. Of Roxane.

7 A. Certainly Mr. Gerstenberg.

8 Q. Can you remember anyone else?

9 A. I'm not -- Again, it was not an active
10 board per se. I think it was more of a legal --
11 legal entity.

12 Q. What do you mean it wasn't an active
13 board?

14 A. There -- Again, very -- You know, it's
15 a number of years ago, so it's hard for me to
16 remember, but as far as I remember there were
17 very, very infrequent meetings and it was more to
18 form than anything else. It wasn't operational
19 in other words.

20 Q. Do you recall any meetings of the
21 Roxane board of directors?

22 A. Not specific.

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1 bottom right-hand corner.

2 Do you recognize this document?

3 A. Not specifically.

4 Q. Do you see on the first page it says,
5 Minutes of the meeting of board of directors,
6 Boehringer Ingelheim Corporation, October 28,
7 1998?

8 A. Yes, I do.

9 Q. I'm going to direct your attention to
10 BIC Juris 0236.

11 A. Okay.

12 Q. Can you please read the first sentence
13 from the paragraph starting, Mr. Berkle.

14 A. Mr. Berkle explained the reorganization
15 of the strategic business unit ethical
16 pharmaceuticals advising that it now has two
17 components, one being generic drugs and the other
18 branded generic drugs.

19 Q. Do you agree that the strategic
20 business unit ethical pharmaceuticals had two
21 components, one being generic drugs and the other
22 branded generic drugs?

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1 A. I -- A slight variation of that. I
2 think this refers to the Roxane component of the
3 strategic business unit. It doesn't refer to the
4 BAPI component, which is purely branded.

5 Q. So there was --

6 A. Really three.

7 Q. I'm sorry. What do you mean by really
8 three?

9 A. Again, this is -- this refers only to
10 Roxane Laboratories.

11 Q. Okay.

12 A. Okay? That's --

13 Q. And so there was a Roxane Laboratories
14 component of the business unit?

15 A. Yes. According to -- According to this
16 anyway definition.

17 Q. The third sentence down in the same
18 paragraph it says, Sales and marketing for
19 branded generics will report to BAPI
20 counterparts. Are branded generics, are those
21 Roxane products?

22 A. Yes, they were.

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1 Q. Why are Roxane sales and marketing
2 reporting to their BIPI counterparts?

3 MR. GASTWIRTH: Objection to form.
4 That's not what this document says.

5 BY MR. FAUCI:

6 Q. Well, I can -- Let's just look at the
7 sentence. It says, Sales and marketing for
8 branded generics will report to BIPI
9 counterparts. Can you tell me what -- what you
10 think that sentence means?

11 A. Well, I can tell you what the situation
12 actually was.

13 Q. Okay. That's --

14 A. Okay. And -- And again, because I
15 certainly can't recall having seen this document,
16 and I certainly didn't write this document.

17 The situation was that there were
18 people within the Roxane organization, within the
19 Roxane business unit, business entity that had
20 responsibility for the day-to-day operations and
21 the various functions, including marketing and
22 sales.

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1 And as I think we talked about
2 previously in the document, just slightly above
3 that particular line, there's two components of
4 the Roxane business, multi-source generic and
5 branded generic.

6 So for the branded generic products
7 there was only a few of them. Those people
8 within the Roxane business entity did report
9 functionally to designated people within the BIPI
10 organization, but the day-to-day operations were
11 still conducted by Roxane people.

12 Q. Okay. The last sentence of this same
13 paragraph reads, The contracting and pricing
14 departments will be combined for ROI and BIPI.
15 Do you recall if this -- if this happened?

16 A. This happened really from the
17 administrative perspective, so that there was --
18 you know, the actual establishment of pricing or
19 contracting was done by individuals within the
20 Roxane business entity, but the processing of the
21 administration, the submission of prices, were
22 done by a central unit within -- within BIPI that

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1 instance?

2 A. Absolutely.

3 Q. Couple paragraphs down it says, Shelly
4 and I -- And this is David Townley writing. He
5 writes, Shelly and I have talked this -- talked
6 through this tonight and he suggested that I
7 approach you directly to request your assistance.

8 Do you recall having a conversation
9 with Mr. Townley in and around the October 1995
10 time frame? I recognize it's a long time ago.

11 A. Not -- Not specifically.

12 Q. Do you have any reason to believe you
13 didn't have a conversation with Mr. Townley as he
14 references in this e-mail?

15 A. No, I do not.

16 Q. I'm going to read a little bit further.
17 What we need from you is a clear strategic
18 outline of overall USA plans with respect --
19 reference to points one, three and four above to
20 also include sales casts for the PEP planning
21 period; i.e., 1996 to 2000.

22 This should be from a total USA

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1 perspective; i.e., BIPI and Roxane combined
2 strategy. For example, how much Ipratropium UDV
3 business can Roxane take from BIPI and how do we,
4 quote, shut out, quote, other non-Bi generics as
5 far as possible? What does it mean for Roxane to
6 take Ipratropium business from BIPI?

7 A. You know, again, it's not my language.
8 You know, I can't tell you specifically what
9 someone else meant or didn't mean by that. So
10 again, strategically the two companies would work
11 together to try to maintain the Ipratropium
12 business whether it be Atrovent or otherwise
13 within the Boehringer family of companies.

14 Q. What did you understand Mr. Townley to
15 mean when he writes this should be from a total
16 USA perspective, i.e. BIPI and Roxane combined
17 strategy?

18 MR. GASTWIRTH: Objection to form.

19 THE DEPONENT: You know, I think I just
20 referred to that. I think -- number one, that
21 this strategy -- this overall strategy referred
22 to as the PEP strategy certainly was broader than

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1 Berkle. We are back on the record.

2 BY MR. FAUCI:

3 Q. Mr. Berkle, I've handed you what the
4 court reporter marked as Exhibit 12. Please take
5 a moment to familiarize yourself with it.

6 A. Okay.

7 Q. See the first page of this document
8 appears to be a fax cover sheet?

9 A. Yes.

10 Q. From Ed Tupa to Mr. Shelly Berkle. Do
11 you see that?

12 A. Yes, I do.

13 Q. Do you recall receiving this document?

14 A. No, I don't.

15 Q. The first paragraph says -- the top of
16 it, the heading, says, Ipratropium Bromide UDV
17 generic launch home health care market meeting
18 summary. Do you see that?

19 A. Yes, I do.

20 Q. And then below that, Roxane
21 Laboratories represented by Tom Via, Jerry Walsh,
22 John Powers, Ed Tupa and consultant Mark Pope,

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1 and Boehringer Ingelheim represented by Scott
2 Richardson, Mike Spitalli and Joe Ashey met to
3 discuss the approaching generic launch of
4 Ipratropium Bromide on January 24th.

5 Tom Via, who's he?

6 A. He was in the marketing department at
7 Roxane Laboratories.

8 Q. Jerry Walsh?

9 A. Jerry was a Roxane employee. I can't
10 remember his specific title or --

11 Q. We've --

12 A. -- position.

13 Q. Sorry. We've already talked about Mr.
14 Powers and Mr. Tupa.

15 A. Correct.

16 Q. Consultant Mark Pope, who is he?

17 A. I have no idea. He's a consultant
18 obviously.

19 Q. Have you ever heard of him?

20 A. I can't recall.

21 Q. And then Boehringer Ingelheim, is that
22 BIP?

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1 A. Yes, it is.

2 Q. And they're represented by three people
3 at this meeting?

4 A. Correct.

5 Q. Why are BIPI personnel at this meeting?

6 A. You know, I think again, you know,
7 Atrovent was a BIPI drug, the brand -- the patent
8 would be expiring. It was anticipated that the
9 two sister companies would work together to best
10 protect the -- or maintain Atrovent or
11 Ipratropium business within the Boehringer
12 family.

13 So I don't think there's anything
14 negative about that. I think it's only natural
15 business that companies try to work together to
16 see how can they maintain the business.

17 Q. The last paragraph, The single latest
18 factor that will influence the success of this
19 product is Dey Laboratories. Do you agree with
20 that?

21 A. Where are you reading from?

22 Q. The very -- First sentence of the very

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1 A. Yes, I do.

2 Q. And we said earlier Mark Pope was
3 identified as a consultant for Roxane. Do you
4 recall that?

5 A. Yes, I do.

6 Q. The third paragraph says, Mr. Pope
7 says, I think it's unrealistic to consider that
8 there will be anywhere near a reasonable amount
9 of brand loyalty for this product given the
10 market dynamics and the nature of competition.
11 The challenge is to get BIPI to, quote, buy into,
12 quote, the long term strategic benefits while
13 relinquishing today's profit dollars and control
14 of the bulk of the product sales.

15 Would there be any long-term strategic
16 benefits to BIPI of relinquishing today's profit
17 dollars?

18 MR. GASTWIRTH: Objection to form.

19 THE DEPONENT: Not to BIPI specific,
20 but if there is a recognition there's going to be
21 other generic competition it would be beneficial
22 to keep the business within the Boehringer

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1 family.

2 BY MR. FAUCI:

3 Q. Beneficial to the whole Boehringer
4 Ingelheim family?

5 A. Correct.

6 Q. Was there -- Were you aware of any
7 strategy to give up or relinquish market share of
8 Atrovent in order to have it moved to Roxane?

9 MR. GASTWIRTH: Objection to form.

10 THE DEPONENT: None that we haven't
11 already discussed. Again, there had been
12 discussion on allowing Roxane to preemptively
13 launch their generic version of Ipratropium
14 Bromide. And as such you obviously -- Atrovent
15 would lose some market share when it was still
16 exclusive.

17 BY MR. FAUCI:

18 Q. But it would be -- that would be
19 beneficial to the whole BI family?

20 A. Correct.

21 Q. That's all with that document.

22 Moving along. I'm going to show you a

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1 is, but it's not going to be within the context
2 of this document specifically.

3 MR. FAUCI: That's fine. Let's just
4 redo this again.

5 BY MR. FAUCI:

6 Q. This strategy costs the innovator
7 company a lot of money. What do you understand
8 it to mean that it was the innovator company?
9 Who do you think that is?

10 A. From a general interpretation of the
11 word "innovator," innovator to me means the
12 original branded product. In this case the
13 original branded product of Ipratropium was
14 Atrovent which was a BIPI product.

15 Q. And how did the strategy of launching
16 Ipratropium Bromide cost BIPI a lot of money?

17 MR. GASTWIRTH: Objection to form.

18 BY MR. FAUCI:

19 Q. Let me try that again. Do you agree
20 that the strategy of launching Ipratropium
21 Bromide, the timing of the launch, cost BIPI a
22 lot of money?

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1 A. Again, in the context that Roxane
2 preemptively launched Ipratropium prior to any
3 other generic competitors had a cost from a BIP
4 perspective. It allowed sales for the Roxane
5 product at a lesser price than the branded price
6 at a time when Atrovent still was patent
7 protected.

Q. I'm going to move on from this document.

I think we're on Exhibit 19. I'm going to have the court reporter mark this.

(Exhibit Berkley 019 was marked.)

THE DEPONENT: Okay.

BY MR. FAUCI:

Q. Was it your prior testimony, and correct me if I'm wrong, that -- that your involvement to the extent you had involvement with Ipratropium Bromide came around the time of its launch?

MR. GASTWIRTH: Objection to form.
Misstates the witness' prior testimony.

MR. FAUCI: It's a question about

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1 A. Yes, I did.

2 Q. And did you notice any correct -- any
3 inaccuracies during that reading?

4 A. Not that I could remember.

5 Q. That's all.

6 I'm going to show you Exhibit 29.

7 (Exhibit Berkle 029 was marked.)

8 MR. GASTWIRTH: And I'll object to the
9 introduction of that deposition -- prior
10 deposition transcript as an exhibit to this
11 deposition.

12 We've got obviously a deposition being
13 conducted in that case, so I'm not going to allow
14 for the admissibility of Mr. Berkle's prior
15 deposition testimony to be used in connection
16 with the deposition that's occurring today. So
17 his testimony today will stand for itself.

18 MR. BREEN: The only concern I've got
19 with that is we've got -- we've got the one day
20 with this witness that has been scheduled, and if
21 I'm going to -- if that's what Roxane is going to
22 do, stand on this not being -- his prior

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1 testimony not being usable in the case, even the
2 issues are the same and everything else, it may
3 significantly extend the amount of time I'm going
4 to need with this witness particularly since this
5 case has been cross-noticed in the Florida case.

6 So -- And I ask you just to reconsider
7 that maybe. I don't want to waste this witness'
8 time, but if I've got to go back and ask him 90
9 percent of the questions, I think that's really
10 unnecessary, but if I have to, I'll have to do
11 it.

12 MR. GASTWIRTH: I'm going to let my
13 objection stay on the record today and we can
14 talk after the conclusion of the deposition.

15 MR. BREEN: Right. Because obviously
16 if I had to do that we're not going to get it
17 done today and we've only scheduled this
18 gentleman for one day as of now. So we can work
19 it out I'm sure, but I just want to make sure
20 it's clear.

21 MR. GASTWIRTH: I understand. I'm
22 still objecting to the introduction.

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1 that this document needs to be revoked on
2 attorney-client or work-product grounds.

3 MR. BREEN: Absolutely. From Ven-a-
4 Care's perspective the fact that you're doing
5 that as an accommodation is appreciated. We will
6 not consider that a waiver or a general waiver of
7 -- of the matter.

8 MR. FAUCI: Nor will the United States.

9 MS. ROGERS: Or the State of Florida.

10 MR. GASTWIRTH: Thank you.

11 BY MR. FAUCI:

12 Q. So moving back, Mr. Berkle. Do you
13 recall that around the 1997 time frame there were
14 discussions about the need to review BIPI and
15 RLI's contracting and pricing processes?

16 MR. GASTWIRTH: Objection to form. Did
17 you say 1999?

18 MR. FAUCI: 1997. Intended to say
19 1997.

20 THE DEPONENT: You know, I don't - I
21 don't remember the specific time frames. Part of
22 the difficulty is you've shown me memos

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1 Q. The first page of this is an e-mail.

2 It's from Dan Gerrity.

3 A. Right.

4 Q. It seems to attach a document about the
5 pricing policy and procedures. Do you see that?

6 A. Yes.

7 Q. It says, Please review the attached
8 draft pricing policy and procedure and provide me
9 any changes you deem appropriate. Do you see
10 that?

11 A. Yes, I do.

12 Q. And this e-mail is dated May 3rd, 2001.
13 Do you see that?

14 A. I do.

15 Q. Let's turn to the pricing policy and
16 procedure document. It says, Scope, this policy
17 is applicable to wholesale acquisition cost,
18 average wholesale price, minimum bid price,
19 direct price for brand products of Boehringer
20 Ingelheim Pharmaceuticals, Inc. and Roxane
21 Laboratories.

22 I had to adjust my microphone there.

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1 Was there a single policy applicable to those
2 prices for brand products of Boehringer Ingelheim
3 Pharmaceuticals and Roxane Labs?

4 MR. GASTWIRTH: Objection. Form.

5 THE DEPONENT: A single policy?

6 BY MR. FAUCI:

7 Q. Let me rephrase that. It says, This
8 policy is applicable to various prices for brand
9 products of Boehringer Ingelheim Pharmaceuticals,
10 Inc. and Roxane Labs. Do you see that?

11 A. Yes, I do.

12 Q. Does it surprise you that there's a
13 document out there that says that there's one --
14 that there's a policy that's applicable to prices
15 for both companies?

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: My understanding of this
18 is that it's applicable to the branded products.
19 Okay. So BIPI and branded generics of Roxane.

20 BY MR. FAUCI:

21 Q. So you think this pertains to a pricing
22 policy for Roxane's branded generics and BIPI's

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1 brand products; is that correct?

2 A. I believe so. And, you know, again my
3 memory isn't a hundred percent, but this was in
4 May of '01, according to the cover memo -- cover
5 e-mail --

6 Q. Cover e-mail. Sure.

7 A. -- and I believe this was approaching
8 the time when we divested of the Roxane branded
9 generic line.

10 Q. What do you mean you divested of the
11 Roxane branded generic line?

12 A. The -- Again, if I recall correctly
13 Viramune, which was under the Roxane label, was
14 transferred to the BIPI label and then the
15 palliative care line was in fact divested sold.

16 Q. To who?

17 A. It was initially sold to Elan who then
18 I know in turn sold it somewhere else. So this
19 was -- you know, this would have been for a very
20 short period of time.

21 Q. What was the -- the drug that you said
22 was transferred to BIPI?

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1 THE DEPONENT: I believe so.

2 BY MR. FAUCI:

3 Q. And do you know if BIPI paid Roxane for
4 Viramune?

5 MR. GASTWIRTH: Objection. Form. This
6 is really -- This is outside of context of this
7 complaint, so --

8 MR. FAUCI: How is it -- Well, I'm not
9 -- I've got one more question on this.

10 THE DEPONENT: I -- You know, I can't
11 answer that definitively. I don't believe so,
12 but I don't know.

13 MR. FAUCI: I'll just state for the
14 record, Roxane's asserted a cooperate veil
15 defense in this case and whether or not Roxane
16 transferred a product to BIPI for fair market
17 value is squarely within the allegations of the
18 complaint. But that's all I have on that.

19 BY MR. FAUCI:

20 Q. Right below it it says pricing
21 approvals. Do you see that?

22 A. Yes.

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1 Q. Recommended prices must be approved in
2 the following sequence. First, PTC committee.
3 Second, executive vice president ethical
4 pharmaceuticals. Is that you?

5 A. Yes, it is.

6 Q. And third, president and CEO of
7 Boehringer Ingelheim Corporation. Who is that?

8 A. That was Mr. Gerstenberg.

9 Q. Mr. Gerstenberg.

10 A. Right.

11 Q. And so according to this document you
12 were supposed to approve prices for BIPPI brand
13 products and Roxane branded generics?

14 MR. GASTWIRTH: Objection. Form.

15 THE DEPONENT: It appears to be.

16 BY MR. FAUCI:

17 Q. And so -- and this policy applies to
18 wholesale acquisition costs?

19 MR. GASTWIRTH: Objection. Form.

20 THE DEPONENT: Yes.

21 BY MR. FAUCI:

22 Q. And average wholesale prices?

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1 MR. GASTWIRTH: Objection.

2 THE DEPONENT: Again, you know, my
3 primary concern was the wholesale acquisition
4 cost and then the details in terms of
5 establishing reference prices was left to others.

6 BY MR. FAUCI:

7 Q. But you had to approve them?

8 MR. GASTWIRTH: Objection. Form.

9 THE DEPONENT: I can't recall
10 specifically exactly what I would have approved,
11 but certainly my focus would be on the WAC.

12 BY MR. FAUCI:

13 Q. When you approve price, what was sent
14 to you?

15 MR. GASTWIRTH: Objection. Form.

16 Approve prices for what?

17 BY MR. FAUCI:

18 Q. Any -- This document is saying that Mr.
19 Berkle recommended prices must be approved in the
20 following sequence. First, PTC committee.
21 Second, executive vice president ethical
22 pharmaceuticals. Was that you, Mr. Berkle?

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1 A. Yes, it was.

2 Q. And this policy is applicable to
3 wholesale acquisition costs and average wholesale
4 prices. That's what it says at the top?

5 A. Yes.

6 Q. When you -- If you were to approve a
7 wholesale acquisition cost or an average
8 wholesale price, what would be sent to you to
9 make the decision on whether or not to approve
10 it?

11 MR. GASTWIRTH: Objection. Form.

12 THE DEPONENT: You know, let me
13 reiterate that I can't recall exactly what was
14 sent to me. My focus was on WAC. It would have
15 been a summary of the information that is listed
16 under pricing proposals.

17 MR. FAUCI: Can you repeat the answer
18 for me.

19 (Record was read by the court
20 reporter.)

21 BY MR. FAUCI:

22 Q. What types of information would be

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1 adjustment.

2 Q. Have you read or seen this before?

3 A. No, I have not.

4 Q. That's all. We're going to do another
5 document.

6 (Exhibit Berkle 034 was marked.)

7 BY MR. FAUCI:

8 Q. The court reporter has handed you
9 what's been marked as Exhibit 34. It's a very
10 lengthy document. Feel free to read it, but I'm
11 going to direct your attention to specific parts
12 of it, so just tell me when you feel ready to
13 have some questions -- have some questions asked.

14 MR. BREEN: Did you already mark this
15 one?

16 MR. FAUCI: Yep. 34.

17 THE DEPONENT: Okay.

18 BY MR. FAUCI:

19 Q. Do you recognize this document?

20 A. Not specifically.

21 Q. Look at the first page. It appears to
22 be an e-mail from Fred Duy. Who's he?

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1 A. Fred was a Roxane employee.

2 Q. And it's sent to you, Shelly Berkle?

3 A. Yes, it is.

4 Q. Subject, Roxicodone 15/30mg launch
5 plan. Do you see that?

6 A. Yes, I do.

7 Q. And then does the attachment to this e-
8 mail appear to be a launch plan for Roxicodone?

9 A. It certainly appears to be at least a
10 summary of a launch plan. Highlights.

11 Q. Is Roxicodone a Roxane product?

12 A. Yes, it was.

13 Q. Second sentence of the e-mail, The
14 strategy is essentially what you saw in
15 Tarrytown. What's Tarrytown?

16 A. It's -- Tarrytown is a town in New York
17 State close -- just across the border from
18 Connecticut.

19 Q. What brought you to Tarrytown?

20 A. I'm sorry?

21 Q. What brought you to Tarrytown?

22 A. Well, there's a conference that was

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1 utilized frequently for meetings by -- by the
2 BIPI people, BIPI/Roxane people.

3 Q. Do you recall -- The strategy is
4 essentially what you saw in Tarrytown. Do you
5 recall being exposed to strategies relating to a
6 launch document in Tarrytown?

7 A. I can't -- I can't remember
8 specifically that meeting. You know, certainly I
9 was at multiple meetings over the years in
10 Tarrytown, but I can't remember the details.

11 Q. It goes on to say that, It--I think the
12 strategy--has been updated and expanded with
13 specific tactics by Doug Bierl with input from
14 lots of people here and in Ridgefield. Who's
15 Doug Bierl?

16 A. I haven't got a clue.

17 Q. What's Ridgefield?

18 A. Ridgefield is the town -- location of
19 BI Pharmaceuticals.

20 Q. Where was Roxane?

21 A. In Columbus, Ohio.

22 Q. Ridgefield means BIPI?

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1 A. It means BIPI, BIC.

2 Q. BIC. Why are people in Ridgefield
3 updating and expanding a strategy for the launch
4 of a Roxane product?

5 MR. GASTWIRTH: Objection. Form.

6 THE DEPONENT: This goes along with
7 some of the memos you've shown me before.
8 Roxicodone was a branded generic and, therefore,
9 there was some supervisory role that some -- a
10 few BIPI people played. But again, the launch
11 plan, as you see here, was put together by Roxane
12 employees.

13 BY MR. FAUCI:

14 Q. It says, We expect approval by the user
15 fee deadline, August 29th. What does that mean?

16 A. I assume that refers to the FDA
17 approval.

18 Q. FDA approval -- The FDA approval of the
19 drug?

20 A. Correct.

21 Q. Okay. Last sentence of that paragraph,
22 If you can fit it into your schedule, we would be

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1 happy to present the launch plan to you and
2 whoever you think is appropriate in Ridgefield.
3 Do you recall if this launch plan was presented
4 to you in Ridgefield?

5 A. I do not recall.

6 Q. Do you recall if you read the launch
7 plan?

8 A. I don't recall specifically if I did or
9 didn't.

10 Q. Do you recall whether you approved the
11 launch of the Roxicodone product?

12 MR. GASTWIRTH: Objection. Form.

13 THE DEPONENT: The way you've said it
14 is basically we put together a data package for
15 FDA approval, which meant that the decision was
16 that we would move ahead once approved to market
17 the drug.

18 So this would have been not just a sole
19 decision on my part. Okay. This would have
20 involved Gerstenberg, Russillo, other people.
21 Medical department, regulatory department.

22 BY MR. FAUCI:

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1 Q. Do you recall if you were one of the
2 people who gave approval for marketing the
3 Roxicodone product?

4 MR. GASTWIRTH: Objection. Form.

5 THE DEPONENT: I -- I believe I
6 certainly was a part of the senior management
7 team that -- that would have heard the
8 recommendation and would have agreed to -- to
9 marketing it.

10 BY MR. FAUCI:

11 Q. I direct your attention to page 23.
12 It's Shaffer 001474. The heading is Market
13 Situation, Market Characteristic Summary.

14 A. Got it.

15 Q. Do you see at the bottom it says price
16 and reimbursement driven. Do you see that?

17 A. I see that.

18 Q. At the top it's market characteristics
19 summary. Do you see that?

20 A. Yes.

21 Q. Let's break that down. What does it
22 mean for something to be price driven?

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1 And in this case, as far as I can see,
2 it -- it allowed -- it was a competitive pricing
3 versus, you know, multiple tablets of a five-
4 milligram Oxycodone on the market. So....

Q. The fact that the suggested AWP for the Roxicodone five-milligram 100s was twice as high as the WAC, that wouldn't have jumped out at you?

8 MR. GASTWIRTH: Objection. Asked and
9 answered.

10 THE DEPONENT: Yeah. I mean, I said,
11 you know, you have to take that in context of
12 what the competitive environment was.

13 BY MR. FAUCI:

14 Q. Mr. Berkle, thank you very much for
15 coming here today.

¹⁶ Oh, I guess I have one more question
¹⁷ for you. I'm sorry.

¹⁸ A Good thing I didn't say you're welcome

¹⁹ (Exhibit Berkley 036 was marked.)

20 THE DEponent: Okay

21 BY MR FAUCI:

²² O Who's Christine Ferrara?

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1 A. Chris was a BIPI employee and was
2 involved in the contract pricing department.

3 Q. Do you recognize this e-mail?

4 A. No, I don't specifically.

5 Q. Do you see that it's an e-mail --
6 there's two e-mails. One's from Christine
7 Ferrara dated August 23rd to Fred Duy. Do you
8 see that?

9 A. Yes, I do.

10 Q. The subject is price?

11 A. Yes.

12 Q. Dear Fred, Shelly assigned the
13 approval, but Werner won't be in until tomorrow
14 at which time I expect that he will review and
15 hopefully approve as well, regards, Chris. Do
16 you see that?

17 A. Yes, I do.

18 Q. And then above it. The top e-mail
19 again is from Christine Ferrara to Fred Duy.
20 It's dated August 24th. Do you see that?

21 A. Yes, I do.

22 Q. It says, Attach, Roxicodone WAC AWP

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1 proposal.doc. Do you see that?

2 A. Yes.

3 Q. Fred, I have received verbal
4 confirmation that the attached pricing has been
5 approved by Shelly and Werner. Do you see that?

6 A. Yes, I do.

7 Q. Does this refresh your --

8 A. No. I mean, I assume it is what it is,
9 but I certainly don't remember.

10 Q. You don't have any reason to think that
11 you didn't, in fact, approve the Roxicodone WAC
12 AWP proposal?

13 MR. GASTWIRTH: Objection. Form.

14 THE DEPONENT: I have no reason to not
15 believe that.

16 MR. FAUCI: For real this time I'll say
17 thank you very much for your testimony. I have
18 no further questions at this time. I reserve the
19 right to ask questions after Mr. Gastwirth if, in
20 fact, Mr. Gastwirth asks questions.

21 MR. GASTWIRTH: Off the record for a
22 minute.

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1 tenure?

2 MR. GASTWIRTH: Objection. Form.

3 THE DEPONENT: Werner Gerstenberg.

4 BY MR. BREEN:

5 Q. And who was the president of BAPI
6 during your tenure?

7 A. There was no president of BAPI.

8 Q. Then who was the chief executive
9 officer that ran the company?

10 A. Again, my position I believe was the
11 highest level position within BAPI reporting to
12 the present CEO of BIC.

13 Q. Okay. So all and all Mr. Gerstenheimer
14 was your boss?

15 A. Mr. Gerstenberg.

16 Q. Gerstenberg. I apologize.

17 Mr. Gerstenberg was your boss?

18 A. Correct.

19 Q. Okay. Now, let's talk a little bit
20 more about Roxane. I've heard your testimony
21 today in response to the Department of Justice's
22 questions, and after going back through the

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1 deposition that we took some time ago, I got -- I
2 gathered a certain impression. I'm going to
3 state that to you and tell me -- I want you to
4 tell me if I'm correct or not.

5 When it came to branded pharmaceuticals
6 being marketed by Boehringer Ingelheim's U.S.
7 operations, you generally had some
8 responsibilities for the sales and marketing
9 aspects?

10 MR. GASTWIRTH: Objection. Form.

11 THE DEPONENT: For the -- You're
12 talking about the branded business within BIPi?
13 BY MR. BREEN:

14 Q. I'm talking about the branded business
15 in general.

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: The --

18 MR. GASTWIRTH: I mean, there are --

19 MS. ROGERS: Please don't make speaking
20 objections.

21 THE DEPONENT: Let me -- Let me just
22 state that throughout my tenure I was responsible

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1 for marketing -- sales and marketing of BIPI
2 branded products. For Roxane branded products I
3 had responsibility for certain periods of time
4 during my tenure.

5 As an example, after year 2000 I had no
6 involvement whatsoever. Oh, I'm sorry, I
7 shouldn't say that. Let me rescind that comment.
8 That after 2000 I had no involvement with Roxane
9 multi-source business whatsoever. I already
10 stated in my previous testimony that sometime
11 after 2000 the Roxane branded business
12 disappeared.

13 BY MR. BREEN:

14 Q. That's because the Roxane corporate
15 entity was turned into a manufacturing entity?

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: The -- Certainly the
18 physical company was a manufacturing site. The
19 Roxane products were combined together with the
20 Ben Venue products under the leadership of Tom
21 Russillo in terms of relative to the marketing
22 and sales and product development, sorry. Also

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1 product development.

2 BY MR. BREEN:

3 Q. And about when was that in 2000?

4 A. I don't remember the specific dates.

5 Q. Do you recall if it was earlier or
6 later in the year?

7 A. You know what, I don't even want to
8 hazard to guess.

9 Q. Why don't you take a look at Exhibit 32
10 -- or 35 which -- What happened to the originals?

11 A. Yeah. It's right here.

12 Q. Thank you.

13 A. Okay.

14 Q. This is dated August 22nd, 2000.

15 A. Right.

16 Q. And this is the one where you and Mr.
17 Gerstenberg are approving Roxicodone prices. Do
18 you see that?

19 A. Yes, I do.

20 MR. GASTWIRTH: Objection. Form.

21 BY MR. BREEN:

22 Q. Is there any doubt in your mind that

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1 what Exhibit 35 is is a document that indicates
2 that you and Mr. Gerstenberg were at least being
3 asked to approve Roxicodone prices?

4 A. I think I testified to that already.

5 Q. Okay. So does this help refresh your
6 recollection as to whether or not by at least
7 August 22nd, 2000 Roxane -- whether or not
8 Roxane's drug products had been combined with Ben
9 Venue?

10 MR. GASTWIRTH: Objection. Form.

11 THE DEPONENT: You know, again, I -- I
12 can't remember. It's just too long ago and
13 there's too many things that have occurred in my
14 -- my work experience that really this was such a
15 -- you know, disappeared from my importance that,
16 you know, I just can't remember the details.

17 BY MR. BREEN:

18 Q. Well, do you have -- do you know
19 whether or not -- Well, strike that.

20 Were you involved in any leadership
21 capacity in the combining of Roxane and Ben
22 Venue's products?

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1 responsibility for setting prices was not
2 management responsibility at Roxane?

3 MR. GASTWIRTH: Objection. Form.
4 Objection. Misstates this witness' prior
5 testimony as well as my prior question of the
6 witness.

7 BY MR. BREEN:

8 Q. All right. Let me restate the
9 question. The fact of the matter is you did from
10 time to time exercise some managerial
11 responsibility with respect to Roxane's
12 operations, at least in the price setting area,
13 didn't you?

14 MR. GASTWIRTH: Objection. Form.

15 THE DEPONENT: For a period of time for
16 the branded generics I -- I approved what was
17 recommended by Roxane management within the
18 Roxane entity.

19 BY MR. BREEN:

20 Q. All right. So let me ask the question
21 so I can overcome counsel's objection like we did
22 earlier. If I ask you if you ever had any

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1 management responsibility at Roxane, would your
2 answer be what you just said?

3 MR. GASTWIRTH: Objection. Form.

4 BY MR. BREEN:

5 Q. Let me ask the question. Did you ever
6 have any managerial responsibility at Roxane?

7 MR. GASTWIRTH: Objection. Form. He's
8 -- He's answered this question a number of times.

9 MR. BREEN: Okay. If it's an asked and
10 answered objection, that's one thing, but if
11 you're objecting to form I'm going to ask it
12 until I get it right.

13 MR. GASTWIRTH: He's answered the
14 question. He said he's had no managerial
15 responsibility over Roxane. He had no day-to-day
16 operational responsibility over Roxane.

17 MR. BREEN: Let's go back because,
18 Counsel, you're misstating his testimony.

19 MR. GASTWIRTH: Okay.

20 BY MR. BREEN:

21 Q. Setting pricing is a managerial
22 responsibility, isn't it?

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1 MR. GASTWIRTH: Let me hear that
2 question back, please. Thank you.

3 (Record was read by the court
4 reporter.)

5 MR. GASTWIRTH: Which company are you
6 speaking of?

7 MR. BREEN: Roxane.

8 THE DEPONENT: I was not involved in
9 the setting of Roxane multi-source products,
10 pricing for multi-source products. I was
11 involved for -- for a period of time approving
12 prices that were recommended by Roxane's senior
13 managers for the branded generic products.

14 BY MR. BREEN:

15 Q. For Roxane, correct?

16 A. For Roxane.

17 Q. And that was a management function,
18 wasn't it?

19 MR. GASTWIRTH: Objection. Form.

20 THE DEPONENT: It was not a day-to-day
21 operational function. It was an occasional
22 responsibility.

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1 Q. Were you -- Was that a management
2 function, sir?

3 MR. GASTWIRTH: Objection. Asked and
4 answered.

5 BY MR. BREEN:

6 Q. Was that a management function, sir?

7 MR. GASTWIRTH: Objection. Asked and
8 answered. You are being argumentative with this
9 witness.

10 MR. BREEN: No. You're being -- You're
11 being -- You are being totally inappropriate,
12 Counsel. I am cross-examining this witness based
13 upon your questions. Now, we can stop and we can
14 we redo this deposition at another time and I'll
15 let the judge rule on this, but he'll let me get
16 an answer to this question. I'll guarantee you.

17 MR. GASTWIRTH: I'll let you get a
18 fourth answer to this question.

19 THE DEPONENT: I will repeat myself. I
20 was not involved in the establishment of prices
21 for the multi-source business. I was involved in
22 approving prices for branded drugs, Roxane

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1 branded generic drugs, which were recommended by
2 senior management at Roxane. If that's how you
3 define managerial responsibility, then that's
4 what it is.

5 BY MR. BREEN:

6 Q. Thank you. And with respect to what
7 you just said you did, with respect to branded
8 drug prices at Roxane, who made the decision as
9 to when you would and when you would not
10 participate managerially with respect to Roxane
11 prices?

12 MR. GASTWIRTH: Objection. Form.

13 THE DEPONENT: You know, I think we
14 spent some time at looking at process, and
15 particularly pertinent to Roxicodone, and I think
16 we saw that the recommended price was asked for
17 approval by myself and Mr. Gerstenberg.

18 BY MR. BREEN:

19 Q. Okay. So you and Gerstenberg decided
20 when you would and when you would not participate
21 in Roxane pricing decisions, correct?

22 A. For --

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1 MR. GASTWIRTH: Objection. Form.

2 THE DEPONENT: For branded generics.

3 BY MR. BREEN:

4 Q. All right. Could you and Mr.
5 Gerstenberg have easily decided that you would
6 exercise some responsibility for multi-source
7 products?

8 MR. GASTWIRTH: Objection. Form.

9 THE DEPONENT: Certainly I could not.

10 BY MR. BREEN:

11 Q. Could Mr. Gerstenberg?

12 A. As country manager, I can't speculate
13 as to what he could or could not do. I can't
14 answer for Mr. Gerstenberg.

15 Q. All right. So what circumstances
16 existed that permitted Mr. Gerstenberg and you to
17 managerially decide when you would participate in
18 the branded pricing actions of Roxane but not
19 participate in the multi-source pricing?

20 MR. GASTWIRTH: Objection. Form.

21 Managerially decided is your term, not this
22 witness'.

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1 THE DEPONENT: Yeah. You know, there
2 was a procedure that was established for branded
3 -- for BIPI brands and for Roxane branded
4 generics that stated that I would approve and Mr.
5 Gerstenberg would approve.

6 BY MR. BREEN:

7 Q. And who established that procedure?

8 A. That was a recommendation by a
9 committee.

10 Q. And the committee was made up of whom?

11 A. People from BIPI and from Roxane.

12 Q. And when was that?

13 A. You know, again, if we looked back at
14 the memos you'd be more definitive in terms of
15 the timing. When was that? That was around,
16 what, '99, 2000, something like that.

17 Q. And the committee's recommendations
18 were made to whom?

19 A. I think you're being redundant here.
20 Did I not already state that the recommendations
21 were made based on the memos I've seen to myself
22 and to Mr. Gerstenberg for branded generics.

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